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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,181	07/26/2001	Felix Theeuwes	DURE-023	9651

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EXAMINER
LAM, ANN Y

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/917,181	Applicant(s) THEEUWES ET AL.	
	Examiner Ann Y. Lam	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-14,17-25 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1, 2, 4, 6-14, 17-25 and 29-31* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 6-14, 17-22, 29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon, 5,842,971.

Yoon discloses an elongate body (18) comprising a proximal end defining an inlet, and a distal end defining an outlet, the elongate body defining a passageway; and a diffuser element (22) operatively associated with the elongate body so as to define a diffusion space (i.e., space occupied by 20), wherein the diffusion space is in fluid communication with the elongate body passageway, see column 9, lines 34-42; wherein a drug at a first concentration is introduced into the elongate body inlet moves through the elongate body passageway, out the elongate body outlet, into the diffusion space, see column 9, lines 38-42, and further wherein fluid from the environment outside the device passes into the diffusion space through the diffuser element, wherein the fluid mixes with the drug, thereby diluting the drug to a second concentration within the diffusion space, and wherein said diluted drug then diffuses out through the diffuser element to exit the device, see column 9, lines 34-44.

As to claim 2, the diffuser element is the diffuser element comprising a material selected from the group consisting of a microporous membrane, see column 9, lines 42-44.

As to claim 4, the elongate body is defined by an exit orifice of a drug delivery device having a diffuser element provided as a cap (22) attached to the exit orifice (48).

As to claim 6, the diffusion space is defined by an outer wall of the elongate body (18) and an inner wall of the diffuser element (22).

As to claim 7, said diffuser element (22) envelops at least a portion of said elongate body (18), see Figure 2.

As to claim 8, the diffuser element is microporous, see column 9, lines 42-44.

As to claim 9, the diffuser element is a dense membrane, see column 9, lines 42-44.

As to claim 10, the diffuser element is an ion-exchange membrane, see column 9, lines 42-44.

As to claim 11, said diffuser element distal end extends distally beyond the elongate body distal end, see Figure 2.

As to claim 12, the diffuser element distal is ring-shaped element, see Figure 2.

As to claim 13, the diffuser element is substantially impermeable to components of biological fluids.

As to claim 14, the diffuser element is selectively permeable to water, see column 9, lines 38-40.

As to claim 17, the elongate body comprises at least two outlets (48).

As to claim 18, the elongate body defines at least two passageways (36A).

As to claims 19 and 24, the elongate body passageway is adapted for delivery of agent at a low volume rate, see column 9, lines 38-44.

As to claim 20, the device is attached to a drug delivery reservoir, see column 9, lines 40-41.

As to claims 21 and 22, the drug delivery device is a convective drug delivery device, and is implantable.

As to claim 25, the drug moves through the elongate body passageway, out the elongate body outlet, into the diffusion space, and further the water from the environment outside the device passes into the diffusion space through the diffuser element wherein the water mixes with the drug, thereby diluting the drug to a second concentration within the diffusion space, and the drug then diffuses out through the diffuser element to exit the device, see column 9, lines 34-44.

As to claim 29, the diffuser element comprises a polymeric film, see column 8, lines 28-33.

As to claim 31, the diffuser element is impermeable to drug and permeable to water, see column 9, lines 38-40.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon, 5,842,971.

Yoon discloses the invention substantially as claimed, except for the diffuser element having a Diffusion Coefficient value in the range between 4.1 x 10-6 and 3.3 x 10-5 ug/cm/sec. However, it would have been obvious to form the diffuser element as described above to have the specific Diffusion Coefficient as claimed, since it would have been obvious to form the diffuser element in a given size or to form the holes in a different size as necessary to accommodate a particular patient or particular medical procedure, see column 33, lines 42-46.

Response to Arguments

Applicant argues that Yoon does not disclose a drug at a first concentration moving through the elongate body passageway and into the diffusion space, wherein fluid from the environment outside the device mixes with the drug, thereby diluting the drug to a second concentration within the diffusion space, before said diluted drug diffuses through the diffuser element to exit the device.

In response, Examiner again points to column 9, lines 38-42, wherein Yoon teaches that in addition to supplying fluid to member (20) passively via contact with body fluids (i.e., dilution of the drug or fluid being delivered, forming a second

concentration within member (20)), the member (20) can be supplied with fluid actively from externally of the body cavity (wherein, the second concentration then exits the device.)

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

09/22/03